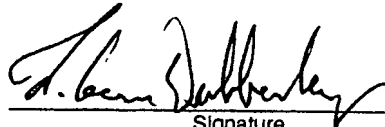
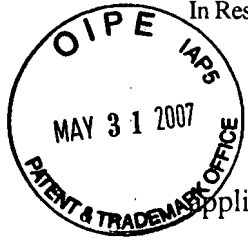




PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 2000.615USD2	
		Application Number 10/698,230	Filed October 31, 2003
		First Named Inventor Min Wan et al.	
		Art Unit 1654	Examiner David Lukton
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>41,001</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p> <p> Signature <u>F Aaron Dubberley</u> Typed or printed name <u>973.325.4542</u> Telephone number <u>May 29, 2007</u> Date</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>			



REASONS FOR REQUESTING REVIEW

The February 26, 2007 Office Action issued in the above-referenced application finally rejects claims 33-38. Each rejection suffers from a clear error or the omission of at least one essential element needed for a prima facie rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections of the claims and the restriction and election requirements. Claims 24-43 are pending in this application, claims 24-32 and 39-43 have been withdrawn from examination and claims 33-38 are examined and were rejected.

Rejection of Claim 33 under the Judicially Established Doctrine of Obviousness-type Double Patenting Fails to Include Any Comparison of Differences in Inventions

Claim 33 has been [provisionally] rejected under the judicially-created doctrine of obviousness-type double patenting over both claim 6 of US Patent No. 6,995,246 and claim 31 of co-pending Application Ser. No. 10/873,801. Applicants respectfully submit that both of these rejections are improper for failing to include an essential element of a prima facie obviousness-type double patenting rejection. Neither rejection provides any comparison of the different limitations of each of the allegedly conflicting claims or makes any statements as to why the differences in the claimed methods would have been obvious to one of skill in the art.

A proper obviousness-type double patenting rejection requires that the Examiner clearly sets forth the alleged differences between the conflicting claims and a reasoning of why the claimed inventions would have been obvious to the skilled artisan.

“Any obviousness-type double patenting rejection **should make clear**:

(A) The differences between the inventions defined by the conflicting claims - a claim in the patent compared to a claim in the application; and

(B) **The reasons why** a person of ordinary skill in the art would conclude that the invention defined in the claim at issue would have been an obvious variation of the invention defined in a claim in the patent.” MPEP §804(II)(B)(1).

In addition, form paragraphs ¶¶ 8.34 and 8.35 following MPEP §804(II)(B) clearly contemplate that the Examiner includes such reasoning as both paragraphs include

the statement; “[A]lthough the conflicting claims are not identical, they are not patentably distinct from each other because,”

Therefore, the Examiner has failed to present a *prima facie* case of obviousness type double patenting because the Examiner has failed to include any comparison and accompanied reasoning with respect to the allegedly conflicting claims. Accordingly, both obviousness type double patenting rejections of claim 33 are clearly improper and withdrawal of these rejections is respectfully requested.

Claims 33-38 Are Not Indefinite Under 35 U.S.C. §112, Second Paragraph, Simply for Depending from Non-elected Claim

Claims 33-38 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rationale for the rejection is given as follows:

“The claims are dependent on a non-elected claim.” See page 6 of the final Office Action.

Applicants submit that depending from a non-elected claim does not make a claim indefinite. There is no uncertainty, whatsoever, as to which limitations are included in the elected claims. For instance, where elected claim 33 depends from non-elected claims 28, 26, 25 and 24, there is no uncertainty that all limitations of claims 24, 25, 26 and 28 are included in elected claim 33.

Preamble Stating Method of “Removing Suspended Particles” Does Not Make Claims 33-38 Indefinite Under 35 U.S.C. §112, Second Paragraph

Claims 33-38 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rationale for the rejection is given as follows:

“... the objective of merely “removing particles” is not consistent with the required process step, i.e., sulfitolysis of sulfhydryl groups. Some

other, more suitable objective of the claimed method should be stated.”
See page 6 of the final Office Action.

With respect to the Examiner’s assertion that the objective of merely “removing particles” is not consistent with the required process step of sulfitolysis of sulfhydryl groups, applicants submit that recital of additional elements in the body of a claim which do not appear in the claim's preamble does not make a claim indefinite under 35 U.S.C. §112, second paragraph. See *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the *Larsen* claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The examiner rejected the claim under 35 U.S.C. §112, second paragraph, because the omission from the claim's preamble of a critical element (i.e., a linear member) renders that claim indefinite. The court reversed the examiner's rejection and stated that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph.

Likewise, the fact that the preamble of the instant claims describe the method as “a method for removing suspended particles from a soluble protein solution” and the claims further require the step of “blocking cysteine residues of the heterologous protein” in the protein solution, does not make the claim indefinite. All of the instant claims require the step of “filtering the soluble protein solution through highly purified diatomaceous earth, thereby providing a clarified soluble protein solution.” Thus, all the instant claims are directed to a method for removing suspended particles from a soluble protein solution ~~and clearly define the claimed subject matter. The term “blocking cysteine residues of~~ the heterologues protein” merely adds a limitation to this method. Accordingly, the preamble is appropriate. For these reasons, the Examiner’s rejection of claims 33-38 as allegedly being indefinite under 35 U.S.C. 112, second paragraph is clearly erroneous and this rejection should be withdrawn.

Rejection of Claims 33-38 under 35 U.S.C. §103(a) Fails to Address All Limitations of the Claims

Claims 33, 34 and 38 remained rejected under 35 U.S.C. §103 as being unpatentable over Hsu (US 6,008,328) in view of Hennen (US 6,468,534) or Colpan (US 6,274,371). Claims 33 - 38 also remained rejected under 35 U.S.C. §103 as being unpatentable over Hsu (US 6,008,328) in view of Bobbitt (US 4,923,967) and further in view of Hennen (US 6,468,534) or Colpan (US 6,274,371). These obviousness rejections are improper for failing to address a positive limitation of the instant claims, therefore failing to state a *prima facie* case of obviousness. The instant claims all require a process “comprising the step of filtering the soluble protein solution through highly purified diatomaceous earth, thereby providing a clarified soluble protein solution”. The clear meaning of this limitation (and particularly the word “thereby”) is that it must be the filtration through diatomaceous earth that provides a clarified soluble protein solution, and not some other filtration step. All the prior art cited against the instant claims teaches diatomaceous earth only as a “filter aid”, and requires some other matrix for the actual filtration step. Accordingly, none of the prior art, taken singly or combined, teaches the instant limitation of a step of diatomaceous earth filtration that results in a clarified soluble protein solution. The Examiner has failed to establish a *prima facie* case of obviousness, and these rejections should be withdrawn.

Restriction and Election Requirements

In the final Office Action of February 26, 2007, applicants’ traverse of the earlier restriction and election requirements is acknowledged and discussed, but the restriction and election are maintained. See pages 2 thru 5 of the final Office Action. Applicants submit that the propriety of this restriction and election *is clearly in error*. As was pointed out in Applicants’ responses of May 9, 2006 and November 17, 2006 and again in a telephone interview with Examiner Lukton on November 16, 2006, *no rationale for the restriction requirement has ever been placed on the record in this application*. There is no statement anywhere in the record why the Examiner considers Restriction Group I (drawn to a method for removing suspended particles from a protein solution, and wherein there is no requirement or suggestion that a cysteine thiol group be blocked)

and Restriction Group II (drawn to the method for removing suspended particles from a protein solution including a further step of blocking a cysteine thiol group) are distinct inventions requiring restriction. Such a statement is an absolute requirement for a valid restriction requirement. See MPEP §803, stating that “[f]or purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown ** by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP §808.02.” In addition, “the examiner, in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the examiner if restriction is not required. See, MPEP §808.02.” The repeated failure to present any such rationale leaves the appearance that the restriction requirement is entirely arbitrary and at the whim of the Examiner. The restriction requirement is therefore clearly improper and should be withdrawn.

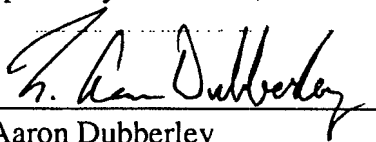
Although Applicants are aware that an improper restriction requirement is not an appealable matter per se but a petitionable matter, it is Applicants belief that review here is warranted because the restriction requirement is clearly erroneous.

The species election requirement is improper for the same reason; *there is no stated reason for the species election*. This species election appears to be entirely at the whim of the Examiner and without any cause in US law or US Patent and Trademark Office procedure. The species election requirement should also be withdrawn.

The panel’s review of this request and withdrawal of all rejections, restrictions and election requirements are respectfully requested.

Dated: May 29, 2007

Respectfully submitted,

By 

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Application No.: 10/698,230

Attorney Docket No.: 2000.615USD2

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